U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			
REQUEST FOR A CORRECTED FILING RECEIPT		Docket No. **12780/102**	Confirm. No. **4719**
Application Number **10/726,029**	Filing Date **December 1, 2003**	Examiner **Vanessa L. FORD**	Art Unit **1645**
Invention Title **VACCINES FOR MYCOPLASMA BOVIS AND METHODS OF USE**		Inventor(s) **Joan Leonard, et al.**	

VIA EFS-WEB
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify this correspondence is being electronically transmitted to the United States Patent and Trademark Office via the Office electronic filing system on July 18, 2008.

Signature: Joseph A. Coppola (Reg. No. 38,413)

Sir:

Applicants respectfully request that the Filing Receipt of the above-identified application be corrected to change the filing date from "12/02/2003" to -- 12/01/2003 -- .

It is respectfully submitted that the above-identified application was filed on December 1, 2003.

In support of this request, enclosed are copies of the following documents:

1. Express Mail Label EV 332525192 US, indicating that the date of deposit of the documents in connection with this application with the U.S. Postal Service was on December 1, 2003;

2. Postcard submitted with the application papers indicating Express Mail Label EV 332525192 US and mailing date of December 1, 2003.

3. Applicants' Application Transmittal indicating the filing date of --December 1, 2003--; and

4. Applicants' Preliminary Amendment which was executed on --December 1, 2003--.

5. A copy of the Updated the Filing Receipt with the changes noted thereon in red.

Since the evidence indicates that Applicants properly deposited the present application under 37 C.F.R. §1.10 using "Express Mail Post Office to Addressee" service with the U.S. Postal Service on December 1, 2003, Applicants respectfully request the Patent Office correct the filing date of the present application to read -- **December 1, 2003** -- on all Patent Office records for this application.

It is believed that no fees are due in connection with this request. However, should any fees be due, the Commissioner is hereby authorized to charge such fees or credit any overpayment associated with this request to Kenyon & Kenyon LLP's Deposit Account **11-0600**.

Dated: July 18, 2008

By: Joseph A. Coppola (Reg. No. 38,413)

KENYON & KENYON LLP
One Broadway
New York, N.Y. 10004
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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/726,029	~~12/02/2003~~ 12/01/2003	1616	538	12780/102	2	37	3

CONFIRMATION NO. 4719

UPDATED FILING RECEIPT

OC000000014629960

26646
KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

Date Mailed: 11/30/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Joan D. Leonard, Olathe, KS;
Robert W. Tully, Olathe, KS;

Power of Attorney: The patent practitioners associated with Customer Number **23859**.

Domestic Priority data as claimed by applicant

This application is a DIV of 09/708,352 11/08/2000
which claims benefit of 60/164,286 11/08/1999

Foreign Applications

If Required, Foreign Filing License Granted: 08/09/2004

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US10/726,029

Projected Publication Date: 03/10/2005

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

Vaccines for Mycoplasma bovis and methods of use

Preliminary Class

424

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

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EV 332525192 US

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Date In: 12/01/03 (Mo. Day Year)	☐ 12 Noon ☐ 3 PM	Postage: $ 17.81
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EMS

EV339525792US 12/1/03 SAC

The sta of the Patent Office hereon, may be ta as 12780/109

acknowledging the receipt, on the date stamped, of

PATENT APPLICATION of Dinsmay Leonard et al

Title Vaccines for Mycoplasma Bovis and Methods of Use

Specifications 26	Assignment —
No. of claims 37	Recording fee $ —
No. of drawings 2	Authorization to charge Dep. Acct. Yes/No
Declaration COPY + POA	Priority Document —
Filing fee $ 538-	Preliminary Amendment YES
Non-Publications request —	Small Entity YES

Statement under 37 CFR

Kenyon & Kenyon

One Broadway

New York, N.Y. 10004

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

UTILITY PATENT APPLICATION TRANSMITTAL LETTER UNDER 37 C.F.R. 1.53(b)	ATTORNEY DOCKET NO.: 12780/102

Address to:
Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Transmitted herewith for filing is the patent application of:

Inventor(s): **Joan D. LEONARD and Robet W. TULLY**

For: **VACCINES FOR MYCOPLASMA BOVIS AND METHODS OF USE**

Enclosed are:

1. **23** sheets of specification, **2** sheets of claims, and **1** sheet of abstract.

2. **2** sheets of drawings.

3. Declaration (copy from prior application (37 CFR 1.63(d) (See 4 below).

4. Incorporation by Reference. The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under paragraph 3 above is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

5. Also enclosed:
   Preliminary Amendment — Statement under 37 C.F.R. 3.73(b)
   Return Receipt postcard — Power of Attorney

6. Continuing application information:

   This application is a divisional of U.S. Patent Application Serial No. 09/708,352 filed on November 8, 2000 which claims benefit of U.S. Patent Application Serial No. 60/164,286 filed on November 8, 1999.

7. Applicant is a small entity and is entitled to small entity status

8. The filing fee has been calculated as shown below, after entry of the

accompanying Preliminary Amendment

	NUMBER FILED		NUMBER EXTRA*	RATE ($)	FEE ($)
BASIC FEE					770.00
TOTAL CLAIMS	37	- 20	17	18.00	306.00
INDEPENDENT CLAIMS	3	- 3=	1	86.00	
MULTIPLE DEPENDENT CLAIM PRESENT				290.00	0.00
*Number extra must be zero or larger				TOTAL	1,076.00
If the applicant is a small entity under 37 C.F.R. §§ 1.9 and 1.27, then divide total fee by 2, and enter amount here.				SMALL ENTITY TOTAL	538.00

10. Please charge the required application filing fee of **$538.00** to the deposit account of **Kenyon & Kenyon**, deposit account number **11-0600**.

11. The Commissioner is hereby authorized to charge payment of the following fees, associated with this communication or arising during the pendency of this application, or to credit any overpayment to the deposit account of **Kenyon & Kenyon**, deposit account number **11-0600**.

A. Any additional filing fees required under 37 C.F.R.§ 1.16;
B. Any additional patent application processing fees under 37 C.F.R. § 1.17;
C. Any additional patent issue fees under 37 C.F.R. § 1.18;
D. Any additional document supply fees under 37 C.F.R. § 1.19;
E. Any additional post-patent processing fees under 37 C.F.R. § 1.20; or
F. Any additional miscellaneous fees under 37 C.F.R. § 1.21.

12. A duplicate copy of this sheet is enclosed.

Dated: DEC. 1, 2003

By: Joseph A Coppola
Joseph A. Coppola (Reg. No. 38,413)

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Attorney Docket No. 12780/102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	Joan D. LEONARD et al.
SERIAL NO.	:	Divisional of 09/708,352
FILING DATE	:	Herewith
FOR	:	VACCINES FOR MYCOPLASMA BOVIS AND METHODS OF USE
EXAMINER	:	To be assigned
GROUP ART UNIT:		To be assigned

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT UNDER 37 C.F.R. §1.115

Sir:

Prior to examination on the merits, please consider the following amendments and remarks.

EV 332525 A2US

IN THE SPECIFICATION:

Page 1, line 2, after the title, please insert the following paragraph:

-- CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of prior U.S. Patent Application Serial No. 09/708,352 filed on November 8, 2002 which claims benefit of U.S. Patent Application Serial No. 60/164,286, filed on November 8, 1999, the disclosures of which are incorporated herein, in their entirety.--

CLAIM AMENDMENTS:

This listing of claims will replace all prior versions and listings of claims in the application:

1-20. (canceled)

21. (new) A method of immunizing bovine animals comprising administering to bovine animals at least one inactivated or attenuated *Mycoplasma bovis* biotype, whereby the incidence of mastitis in the bovine animals is reduced.

22. (new) The method of claim 21 comprising administering at least one inactivated *Mycoplasma bovis* biotype to a plurality of cows in a herd of cows and determining that the incidence of mastitis caused by *Mycoplasma bovis* in the herd before administering was greater than the incidence of mastitis caused by *Mycoplasma bovis* in the herd after administering.

23. (new) The method of claim 22 comprising administering at least one inactivated *Mycoplasma bovis* biotype to at least about 50% of the herd.

24. (new) The method of claim 21 where the inactivated or attenuated *Mycoplasma bovis* biotype is administered together with an adjuvant.

25. (new) The method of claim 24 where the adjuvant is an aluminum hydroxide-oil emulsion; a mineral, vegetable, or fish oil-water emulsion; a water-oil-water emulsion; incomplete Freund's adjuvant; *E. coli* J5; dextran sulfate; iron oxide; sodium alginate; Bacto-Adjuvant; a synthetic polymer; Carbopol; a poly-amino acid; a co-polymer of amino acids; saponin; carrageenan; REGRESSIN®; N, N-dioctadecyl-N'-N'-bis(2-hydroxyethyl) propanediamine; a long chain polydispersed β(1,4) linked mannan polymer interspersed

with O-acetylated groups; deproteinized cell wall extracts from a non-pathogenic strain of *Mycobacterium*; mannite monooleate; paraffin oil; or muramyl dipeptide.

26. (new) The method of claim 21 where the inactivated or attenuated *Mycoplasma bovis* biotype is administered together with a pharmaceutically acceptable excipient.

27. (new) The method of claim 21 where the inactivated or attenuated *Mycoplasma bovis* biotype is administered orally, intranasally, intratracheally, intramuscularly, intamammarily, subcutaneously, intravenously, or intradermally.

28. (new) The method of claim 21 where the inactivated or attenuated *Mycoplasma bovis* biotype is administered by injection, inhalation, ingestion, or infusion.

29. (new) The method of claim 21 where the *Mycoplasma bovis* biotype has been inactivated

30. (new) The method of claim 29 where the *Mycoplasma bovis* biotype has been inactivated by treatment with: formalin, azide, freeze-thawing, sonication, heat, sudden pressure drop, detergent, lysozyme, phenol, proteolytic enzymes, β-propiolactone, Thimerosal, or binary ethyleneimine.

31. (new) The method of claim 30 where the *Mycoplasma bovis* biotype has been inactivated by treatment with β-propiolactone.

32. (new) The method of claim 21 where at least two inactivated *Mycoplasma bovis* biotypes are administered.

33. (new) The method of claim 32 where the at least two inactivated *Mycoplasma bovis* biotypes are selected from the group consisting of Biotype A, Biotype B, and Biotype C.

34. (new) The method of claim 32 where at least 10^8 cell equivalents of each *Mycoplasma bovis* biotype are administered.

35. (new) The method of claim 32 where approximately 10^8 cell equivalents of each *Mycoplasma bovis* biotype are administered.

36. (new) The method of claim 32 where at least approximately 10^5 cell equivalents of each *Mycoplasma bovis* biotype are administered.

37. (new) The method of claim 32 where approximately 10^5 cell equivalents of each *Mycoplasma bovis* biotype are administered.

38. (new) The method of claim 32 where the at least two inactivated *Mycoplasma bovis* biotypes are administered separately.

39. (new) The method of claim 21 where at least two inactivated *Mycoplasma bovis* biotypes and an antigen derived from another pathogen are administered.

40. (new) The method of claim 39 where the antigen from another pathogen is from an attenuated or inactivated virus.

41. (new) The method of claim 39 where the antigen from another pathogen is selected from the group consisting of antigens from *Staphylococcus aureus, Pasteurella hemolytica, Pasteurella multocida, Hemophilus somnus*, Bovine Respiratory Syncytial Virus, *E. coli*, and the organism causing Infectious Bovine Rhinotrachial Disease.

42. (new) The method of claim 32 where the at least two inactivated *Mycoplasma bovis* biotypes are genetically different as determined by an analysis of DNA or RNA from the biotypes.

43. (new) The method of claim 42 where the analysis is PCR fingerprinting, analysis of ribosomal RNA, or analysis of DNA polymorphisms.

44. (new) The method of claim 43 where the analysis is by PCR fingerprinting.

45. (new) The method of claim 44 where the PCR fingerprinting uses arbitrarily chosen primers.

46. (new) The method of claim 44 where the PCR fingerprinting uses as primers 5' NNN NCG NCG NCA TCN GGC 3' (SEQ ID NO:1) and 5' NCG NCT TAT CNG GCC TAC 3' (SEQ ID NO:2).

47. (new) The method of claim 32 where the at least two *Mycoplasma bovis* biotypes have been identified as being different biotypes by a process comprising:
(a) isolating DNA from the biotypes;
(b) amplifying the DNA by PCR;
(c) separating the amplified DNA by gel electrophoresis; and
(d) comparing the resulting patterns from the gel electrophoresis to identify the different biotypes.

48. (new) The method of claim 32 where the at least two *Mycoplasma bovis* biotypes are administered in a specific ratio.

49. (new) The method of claim 32 where the at least two *Mycoplasma bovis* biotypes are grown separately as pure cultures, inactivated, and combined together in equal amounts before being administered to the animal.

50. (new) A method for immunizing bovine animals comprising administering to bovine animals an antigenic component from at least one inactivated or attenuated *Mycoplasma bovis* biotype, whereby the incidence of mastitis in the bovine animals is reduced.

51. (new) The method of claim 50 where antigenic components from at least two *Mycoplasma bovis* biotypes are administered.

52. (new) The method of claim 21 where the administering results in greater milk production, greater weight gain, or less clinical disease in the bovine animal.

53. (new) A method of immunizing bovine animals comprising:
(a) testing samples from bovine animals for the presence of *Mycoplasma bovis* biotypes, thereby identifying specific *Mycoplasma bovis* biotypes in the samples;
(b) preparing a vaccine by inactivating at least 10^5 cell equivalents of at least one of the *Mycoplasma bovis* biotypes identified in step (a); and
(c) administering to the bovine animals the vaccine of step (b),
whereby the incidence of mastitis in the bovine animals is reduced.

54. (new) The method of claim 53 where the sample is milk.

55. (new) The method of claim 53 where step (a) comprises genetic analysis of DNA or RNA from the *Mycoplasma bovis* biotypes.

56. (new) The method of claim 55 where the genetic analysis is PCR fingerprinting, analysis of ribosomal RNA, or analysis of DNA polymorphisms.

57. (new) The method of claim 56 where the genetic analysis is PCR fingerprinting.

Remarks

This application was filed to pursue non-elected subject matter that was subject to a restriction requirement during prosecution of the parent application, U.S. Patent Application Serial No. 09/708,352. See the Office Action dated August 24, 2001, where claims 13-17 and 20, directed to methods of immunizing cattle against disease caused by *Mycoplasma bovis* (Group II) were subject to restriction. The Applicants subsequently chose to prosecute the claims of Group I. This Preliminary Amendment presents a new set of claims directed to subject matter of Group II.

New claims 21-57 are supported in the specification as follows:

New claim 21

Support is found in the specification at page 18, line 24 to page 20, line 17 and at page 20, line 20 to page 21, line 25 (see in particular page 21, lines 11-12).

New claim 22

Support is found in the specification at page 18, line 24 to page 19, line 31.

New claim 23

Support is found in the specification at page 23, lines 1-2.

New claim 24

Support is found in the specification at page 8, lines 7-8.

New claim 25

Support is found in the specification at page 8, lines 16-26 and page 11, lines 3-4. A water-oil-water emulsion is disclosed at Example 2, part D ("Adjuvanting and Formulation of Vaccine"), page 17, lines 17-19, where in step 7 it is disclosed that an oil adjuvant is

added to the inactivated *M. bovis* so as to produce a vaccine with 4% to 12% oil. One skilled in the art would understand that such a low amount of oil in the vaccine would not be enough to completely surround the aqueous phase of the vaccine and thus one skilled in the art would understand this passage to be a disclosure of an water-oil-water emulsion.

New claim 26

Support is found in the specification at page 10, line 22.

New claim 27

Support is found in the specification at page 9, lines 3-4.

New claim 28

Support is found in the specification at page 9, lines 4-6.

New claim 29

Support is found in the specification at page 4, lines 10-19.

New claim 30

Support is found in the specification at page 4, lines 13-17.

New claim 31

Support is found in the specification at page 4, lines 17-19 and page 16, lines 22-28.

New claim 32

Support is found in the specification at page 5, lines 23-25 and page 9, lines 1-2.

New claim 33

Support is found in the specification at page 5, lines 22-23.

New claim 34

Support is found in the specification at page 7, lines 12-13.

New claim 35

Support is found in the specification at page 10, line 5 and page 10, line 8.

New claim 36

Support is found in the specification at page 10, line 12.

New claim 37

Support is found in the specification at page 10, line 17.

New claim 38

Support is found in the specification at page 9, lines 20-22.

New claim 39

Support is found in the specification at page 5, lines 25-27.

New claim 40

Support is found in the specification at page 7, line 31.

New claim 41

Support is found in the specification at page 8, lines 1-5.

New claim 42

Support is found in the specification at page 5, lines 12-13, Figures 1 and 2.

New claim 43

Support is found in the specification at page 12, lines 6-28; Figures 1 and 2; and page 5, line 13.

New claim 44

Support is found in the specification at page 12, line 4 to page 14, line 13.

New claim 45

Support is found in the specification at page 12, line 10.

New claim 46

Support is found in the specification at page 12, lines 13-14.

New claim 47

Support is found in the specification at page 12, lines 15-28; and Figures 1 and 2

New claim 48

Support is found in the specification at page 7, lines 2-4.

New claim 49

Support is found in the specification at page 10, lines 23-27.

New claim 50

Support is found in the specification at page 7, lines 4-7.

New claim 51

Support is found in the specification at page 7, lines 4-7.

New claim 52

Support is found in the specification at page 9, line 31 to page 10, line 1.

New claim 53

Support is found in the specification at page 14, lines 21-31; page 15, line 20 to page 16, line 19; page 18, line 24 to page 19, line 15.

New claim 54

Support is found in the specification at page 14, lines 21-31.

New claim 55

Support is found in the specification at page 5, lines 12-13; and Figures 1 and 2.

New claim 56

Support is found in the specification at page 12, lines 6-28; Figures 1 and 2; and page 5, line 13; Figures 1 and 2.

New claim 57

Support is found in the specification at page 12, line 4 to page 14, line 13; Figures 1 and 2.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

Respectfully submitted,

Dated: DEC. 1, 2003

Joseph A. Coppola
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